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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,819	11/30/2006	Richard Beliveau	067043-5005	7191

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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07/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,819	Applicant(s) BELIVEAU ET AL.	
	Examiner Vera Afremova	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/19/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Group V (claims 19-23) in the reply filed on 3/26/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-13 have withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention(s), there being no allowable generic or linking claim.

Claims 14-18 were canceled by applicants.

Claims 19-23 as amended (3/26/2009) are under examination in the instant office action.

Claim Rejections - 35 USC § 112

Claims 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 as amended is rendered indefinite by the phrase “a mixture of bacterial strain”. This phrase encompasses a mixture but refers to one strain (not strains). Thus, it is uncertain whether the mixture is intended for cells derived from one strain either *L. acidophilus* or *L. casei* or whether the mixture would be made from both strains *L. acidophilus* and *L. casei*. The specification describes the use of “at least one” (page 2, line 11) and, thus, it does not provide a clear guidance for the instant claims as presently amended.

Further, with respect to claim 19 as amended the required components of the therapeutic composition are not particularly clear. Is it a mixture of strain(s) cells in a medium? Is it a

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mixture of microbial cells together with a broth? What is “a whole broth”? Is this “broth” a medium? Is this “broth” a medium fermented by strain(s)? It is not clear whether the claim encompasses additional admixture of same strain cells to the already fermented medium (whole broth)?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19-23 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,491,956 (Heo et al.).

Claims are directed to a method for prevention or treatment of an angiogenesis dependant disorder, wherein the method comprising one active step of administering to a mammal an effective amount of a lactic composition comprising a mixture of bacterial strains selected from *Lactobacillus acidophilus* and *Lactobacillus casei* and whole broth of said mixture. Some claims are further to the mammal being a human. Some claims are further to oral administration of the composition. Some claims are further to the disorder selected from the group consisting of retinopathy, infantile haemangioma, rheumatoid arthritis, psoriasis, duodenal ulcers, post-angioplasty restenosis and tumor growth.

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US 6,491,956 (Heo et al.) teaches a method for prevention or treatment of *Helicobacter* infection related disorders including duodenal ulcers (entire document including examples 10, 11 and 16). The cited method comprising one active step of oral administration to mammals including mice and humans an effective amount of a milk product fermented by a combination of *Lactobacillus acidophilus* with *Lactobacillus casei* that is “a mixture of bacterial strains selected from *Lactobacillus acidophilus* and *Lactobacillus casei* and whole broth of said mixture” within the meaning of the claims. Prevention and/or treatment of duodenal ulcers are explicitly acknowledged by the cited reference (col. 17, line 34, for example). With respect to other claimed disorders it is noted that the cited method comprises same one active step of administering same lactic composition to same generic patient as required by the claimed method and, thus, the effects of practicing identical protocols are reasonably expected to be the same.

Therefore, the cited reference is considered to anticipate the presently claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,491,956 (Heo et al.), Konturek et al. (Regulatory Peptides. 2000, Vol. 93, No. 1-3, pages 13-19) and WO 03/045405 (IDS reference).

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Claims are directed to a method for prevention or treatment of an angiogenesis dependant disorder, wherein the method comprising one active step of administering to a mammal an effective amount of a lactic composition comprising a mixture of bacterial strains selected from *Lactobacillus acidophilus* and *Lactobacillus casei* and whole broth of said mixture. Some claims are further to the mammal being a human. Some claims are further to oral administration of the composition. Some claims are further to the disorder selected from the group consisting of retinopathy, infantile haemangioma, rheumatoid arthritis, psoriasis, duodenal ulcers, post-angioplasty restenosis and tumor growth.

US 6,491,956 (Heo et al.) teaches a method for prevention or treatment of *Helicobacter* infection related disorders including duodenal ulcers (entire document including examples 10, 11 15 and 16). The cited method comprising one active step of oral administration to mammals including mice and humans an effective amount of a milk product fermented by a combination of *Lactobacillus acidophilus* with *Lactobacillus casei* that is “a mixture of bacterial strains selected from *Lactobacillus acidophilus* and *Lactobacillus casei* and whole broth of said mixture” within the meaning of the claims. Prevention and/or treatment of duodenal ulcers are explicitly acknowledged by the cited patent US 6,491,956 (col. 17, line 34, for example). Although the cited patent US 6,491,956 (Heo et al.) is silent with respect to other claimed disorders it is well known that *Helicobacter* infection is accompanied by inflammation, carcinogenesis, angiogenesis and tumor growth as adequately evidenced by the reference by Konturek et al. (see abstract, for example).

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WO 03/045405 is relied for the teaching about using combination of strains belonging to *Lactobacillus acidophilus* and *Lactobacillus casei* in compositions and methods for preventing and treating cancer and tumor growth (entire document including abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to administer a combined *Lactobacillus acidophilus* and *Lactobacillus casei* product with a reasonable expectation of success in prevention or treatment of angiogenesis dependant disorders including tumor growth because a combined *Lactobacillus acidophilus* with *Lactobacillus casei* products have been known and used for preventing and treating cancer and tumor growth (WO 03/045405) as well as for prevention or treatment of *Helicobacter* infection related disorders including inflammation, carcinogenesis, angiogenesis and tumor growth (US 6,491,956 (Heo et al.) and Konturek et al.). Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

July 13, 2009

/Vera Afremova/

Primary Examiner, Art Unit 1657